

Remarks

Claims 1-40 are pending. Claims 35-40 remain withdrawn from consideration.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-34 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention. In particular, the Examiner states that

there is no evidence that there is any structure/function relationship between the polyanionic components disclosed and all the existing polyanionic components covered under the general phrase of "the first polyanionic component having the first molecular weight and the second polyanionic component having a second molecular weight."

Applicant respectfully traverses the rejection.

Applicant respectfully submits that the present claims, and claims 1-34 in particular, are properly described in the specification to convey that the inventor(s) had possession of the claimed invention, as well as being sufficiently described to enable a person of ordinary skill in the art to practice the invention.

As noted in the Federal Register regarding the guidelines to be used by the USPTO personnel in their review of patent applications for compliance with the "written description"

requirement of 35 U.S.C. § 112, first paragraph, "there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." (66 Fed. Reg. 1099, 1105). "An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." (66 Fed. Reg., Supra).

Applicant submits that the present claims are sufficiently described with sufficient relevant, identifying characteristics to demonstrate to a person of ordinary skill in the art that the inventor had possession of the claimed invention. For example, the paragraph beginning at page 2, line 30 of the present specification discloses ophthalmic compositions comprising an ophthalmically acceptable carrier component and a polyanionic component including at least two polyanionic component portions, each portion having a different molecular weight. The last sentence of that paragraph states that each of the portions is preferably present in an amount of at least about 0.1% w/v of the composition. In addition, examples of suitable polyanionic components useful in the claimed compositions are disclosed at page 3, line 25 to page 4, line 14 of the present specification. Additional examples of polyanionic components are described at page 7, line 19 to page 9, line 11 of the present specification. Furthermore, specific examples of compositions in accordance with the embodiments of the claimed invention are provided from page 16 to page 21. The specification also states that one embodiment of the composition includes first and second polyanionic component portions having different molecular weights, but substantially similar chemical structures (page 7,

lines 7-11). However, suitable polyanionic component portions may also have different chemical structures (page 7, lines 11-12).

Applicant further submits that the additional limitations recited in the present claims are similarly sufficiently described in the specification to satisfy the requirements of 35 U.S.C. § 112, first paragraph.

Regarding the Examiner's specific statement that there is no specific structure/function relationship, as indicated above, applicant submits that such a relationship is not required to satisfy 35 U.S.C. § 112. Nevertheless, applicant also submits that the specification does disclose sufficient relationships between the first polyanionic component portion and the second polyanionic component portion. For example, as set forth in the present specification, each of the polyanionic component portions has more than one discrete anionic charge (page 5, lines 31-32) and has different molecular weights (page 6, lines 2-3). A composition comprising a combination of a first polyanionic component portion and a second polyanionic component portion, as recited in the present claims, may have a reduced ability to cause blurriness of vision in an eye relative to a substantially identical composition having an equal total amount of the polyanionic component and substantially no second polyanionic component portion (page 6, lines 25-30).

Thus, applicant submits that the present specification not only contains sufficient description to convey that the inventor(s) had possession of the claimed invention, it also contains sufficient description to enable a person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention as required by 35 U.S.C. § 112, first paragraph.

In view of the above, applicant submits that the present claims are sufficiently described in the present specification to satisfy the requirements of 35 U.S.C. § 112, first paragraph. Therefore, applicant respectfully requests that the rejection of claims 1 to 34 based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 103


Claims 1-34 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Refresh Liquigel<sup>TM</sup>: A New Approach to the Treatment of Persistent Dry Eye, Therapeutic Reporter, p. 68-71, (2002), as submitted in the Supplemental Information Disclosure Statement filed on July 10, 2003. The author of this reference is Simmons, P.A. and for purposes of convenience, applicant will refer to this reference as Simmons.

Applicant respectfully traverses the rejection. Among other things, Simmons is not prior art with respect to the present application. Simmons was published in 2002. The above-identified application was filed on December 14, 2001. Because Simmons is not prior art, applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, and the rejection over Simmons should be withdrawn.

In conclusion, applicant has shown that the present specification is in proper form, that the present claims satisfy

the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-34 are allowable. Therefore, applicant requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

Date: NOVEMBER 12, 2003   
Frank J. Uxa  
Attorney for Applicant  
Registration No. 25,612  
4 Venture, Suite 300  
Irvine, California 92618  
(949) 450-1750  
(949) 450-1764 Facsimile